REMARKS

Reconsideration and allowance of pending claims 26-29 and 32 is respectfully requested. Claims 26 and 32 have been amended, support for which can be found throughout the application as filed. In particular, support can be found in the specification at page 13, lines 20-29 and pages 53-54. Applicant submits that no new matter will be introduced into the application as filed upon entry of the amended claims. Therefore, entry of the amendment is requested.

Claims 28 and 32 were rejected under 35 U.S.C. § 102(e) as being anticipated U.S. Patent No. 6,075,179 to McCormack et al. (hereinafter McCormack '179). The Examiner asserts that McCormack '179 discloses co-extruded multilayer films that are breathable, are antimicrobial in nature, and provide a barrier to liquids. The Examiner further asserts that the film layers of McCormack '179 read on Applicant's microporous adhesive D layer and monolithic C layers. Applicant traverses this rejection for at least the following reasons.

McCormack '179 discloses multilayer film structures useful in the manufacture of articles requiring vapor permeability, liquid impermeability, and adhesive characteristics. *See* McCormack '179 at column 13, lines 23-30. All of the Examples of McCormack '179 teach the desirability of laminate film structures having particular water vapor transmission rates. McCormack '179 is silent with respect to laminates comprising microporous adhesive core layers that exhibit any particular amount of microvoids upon stretching.

By contrast, the claims recite multilayer breathable films providing a barrier to microorganisms and a barrier to blood and bodily fluids. The claimed microporous adhesive core layer comprises micropores constructed and arranged to permit the passage of gaseous

water and to provide a barrier to the passage of liquid water, and particulate filler having an average particle size between about .8 microns and about 3 microns. When stretched, the claimed microporous adhesive the core layer has at least 27.6% microvoids.

McCormack '179 does not teach the claimed percentage of microvoids. Therefore, McCormack '179 fails to teach each and every claimed element, and accordingly, does not anticipate the claims. Applicant respectfully submits that the Section 102-based rejection over McCormack '179 should be withdrawn.

Claims 26-29 stand rejected under 35 U.S.C. § 103(a) over U.S. Patent No. 5,560,974 to Langley (hereinafter Langley '974) in view of U.S. Patent No. 5,653,699 to Reed et al. (hereinafter Reed '699). The Examiner asserts that although Langley '974 discloses Applicant's claimed microporous core layer, but not Applicant's outer monolithic film layer, a skilled artisan would combine the monolithic material of Reed '699 with the teachings of Langley '974 to "produce the laminate structure of Langley with the most optimal barrier to penetration by liquids". *See* outstanding Office Action at page 4. Applicant traverses this rejection for at least the following reasons.

Langley '974 discloses a breathable non-woven composite fabric and a fabrication process for preparing this fabric. The non-woven composite fabric of Langley '974 is constructed of a microporous thermoplastic film having at least one film surface thermally bonded to a layer of non-woven thermoplastic materials. Such non-woven composite fabric provides a barrier to the passage of biological fluid. *See* Langley '974 at col. 4, lines 5-12. While this reference does teach a microporous thermoplastic film layer, Langley '974 is silent

with respect to the size of filler particles or amount of microvoids present in such as microporous thermoplastic film layer.

Moreover, Langley '974 does not teach a composite fabric having an outer monolithic film layer. To the contrary, Langley '974 teaches that spun bonded non-woven layers are superior to film materials as outer layers, because spun bonded non-woven layers provide composite fabrics with a cloth-like surface texture which enhances the use of the fabric in garments. This desirable cloth-like surface texture is contrasted with the smooth plastic surface characteristic of film materials. *See* Langley '974 at col. 6, lines 3-10. Thus, Langley '974 discredits the use of film outer layers in favor of spun bonded non-woven layers.

Our courts have long held that obviousness cannot be established by combining the teachings of various references to produce the claimed invention, absent some teaching, suggestion, or incentive supporting the combination of references. Carela v. Starlight Archery, 804 F.2d 135 (Fed. Cir. 1986). The critical inquiry is whether there is something in the cited art as a whole to suggest the desirability, and thus its obviousness, in making the combination. In re Newell, 891 F.2d 899 (Fed. Cir. 1989).

Accordingly, the mere fact that Langley '974 might possibly be modified to employ a film surface layer does not make the modification obvious unless Langley '974 suggests the desirability of the modification. Here, Langley teaches that film surface layers are not desirable. Thus, the primary reference, Langley '974, actually teaches away from the Examiner's hypothetical combination of the outer monolithic film layer of Reed '699 and the core microporous thermoplastic film of Langley '974 to form a composite laminate structure.

The text of Langley '974 contradicts the Examiner's assertion that a skilled artisan would be motivated to combine the teachings of Langley '974 and Reed '699 to "produce the laminate structure of Langley with the most optimal barrier to penetration by liquids". Only by defeating the purpose of Langley '974, which is to provide a laminate fabric having a cloth-like surface texture, can the Examiner make this assertion. Such logic is impermissible for establishing a *prima facie* case of obviousness. *See* In re Gordon, 733 F.2d 900 (Fed. Cir. 1984).

Even if, *arguendo*, a skilled artisan were to make the hypothetical combination of Langley '974 with Reed '699, Reed '699 fails to compensate for the deficiencies of Langley '974. Reed '699 fails to teach the claimed microporous adhesive core layer, which comprises particulate filler having an average particle size between about .8 microns and about 3 microns and is constructed and arranged to provide the passage of gaseous water but substantially prevent the passage of liquid water. Reed is silent with respect to a microporous adhesive core layer that when stretched exhibits at least 27.6% microvoids.

Applicant also notes that the film layer of Reed '699 is not "co-extruded" with the exudate transport layer, but is preferably "cast as a thin, continuous, monolithic film of desired thickness from a solvent" to produce a film having a differential wet-to-dry MVTR ratio greater than 1. *See* Reed '699 at col. 9, lines 42-54. This cast film is then laminated to the separately prepared exudate transport layer to form the basic Reed '699 structure.

Moreover, Applicant respectfully notes that Reed '699 teaches that the overall thickness of the laminate structure can exceed ½ inch, with the single polymeric film typically comprising more than 1 mil to 5 mil of that thickness, and preferably 1.5-2.0 mils.

See Reed '699 at col. 16, lines 31-42. The Examiner states that Reed '699 also teaches monolithic layers of a little as 0.1 mil. *See* outstanding Office Action at page 8. Although Example 1 of Reed '699 notes that a series of films were prepared having a dry thickness ranging from about 0.1 mil to about 20 mil, only the physical properties of films having a thickness of about 1.3 to 1.5 mil were measured in the Examples. The only physical properties measured were tensile strength at break, elongation at break, wet moisture vapor transfer rate (MVTR) and dry MVTR. Microbial permeability was not tested.

No functionality was suggested, much less demonstrated, for films having less than a thickness of about 1.0 mil. Reed '699 does not teach that polymeric film layers having a thickness of 0.1 mil are capable of providing a level of MVTR necessary for use in wound dressings. Figure 4 of Reed '699 only provides evidence of wet MVTR values for single film layers having a minimum thickness of 1 mil. *See* Reed '699 at col. 11, lines 35-47. Merely spreading a thin film on a slide simply does not teach a monolithic film layer suitable for use in a laminate structure having particular functional characteristics, specifically providing a barrier to microorganisms. Thus, the only films of Reed '699 that are shown to be enabled are those having a thickness greater than 1 mil, which exhibit a differential wet-to-dry MVTR ratio greater than 1.

The single film layer of 1.5-2.0 mils disclosed by Reed '699 is more than 10 times the thickness of the monolithic layers described in the representative Examples of the instant specification. The instant representative Examples typically have a *total* thickness of less than 1 mil, not merely a single layer of this thickness. This feature further underscores the

fundamental differences in both structure and function between the laminate structure of Reed '699 and the claimed trilayer film.

Applicant respectfully submits, therefore, that the teachings of Reed '699, in hypothetical combination with Langley '974, do not provide the necessary motivation to one of ordinary skill to make the claimed breathable multilayer films having the claimed volume ratios. A skilled artisan simply would not turn to Reed '699 as a means of modifying the laminate structure of Langley '974 to achieve multilayer breathable films having outer monolithic film layers in the claimed volume ratios. Further, although not conceding that such motivation exists, Applicant respectfully contends that even if the Examiner's proposed combination were made in accord with the teachings of the cited references, the resulting structure would remain substantially different than the claimed multilayer breathable film.

In view of the aforementioned points, Applicant respectfully submits that the Examiner has failed to establish a *prima facie* case of obviousness, and that the Section 103-based rejection of the claims over the combination of Langley '974 and Reed '699 should be withdrawn.

Claims 26-29 were rejected under 35 U.S.C. § 103(a) as being unpatentable over McCormack '179. The Examiner asserts that McCormack '179 discloses the claimed invention, but does not teach the claimed volume ratios. Nevertheless, the Examiner asserts that the claimed multilayer breathable films would be obtained by optimizing the ratios of the layers taught by McCormack '179. Applicant respectfully traverses

McCormack '179 is not prior art to the instant application under 35 U.S.C. § 103(c). Pursuant to 37 C.F.R. 1.53(d), the instant CPA has a filing date after November 29, 2000. The

subject matter of McCormack '179 was subject to an obligation of assignment to the same entity, Kimberly Clark Worldwide, Inc. (the parent of which is Kimberly-Clark Corporation) as the instant invention at the time the instant invention was made. Therefore, McCormack '179 is excluded as prior art to the instant application. Applicant respectfully submits that the Section § 103(a)-based rejection over this reference should be withdrawn.

Claims 26-29 and 32 were rejected under 35 U.S.C. § 103(a) as being unpatentable over McCormack '179 in view of Reed '699. The Examiner states that "[t]he monolithic layer of Reed is known to produce visually clear films". *See* outstanding Office Action at page 6. The Examiner asserts that it would have been obvious to combine the monolithic layer of Reed '699 with the laminate structure of McCormack '179 to achieve a laminate having the color of the core layer. *Id.* The Examiner also asserts that although the combination of McCormack '170 and Reed '699 do not disclose the claimed volume ratios, it would have been obvious to obtain such ratios based on optimizing the teachings of the cited references. *Id.* Applicants traverse this rejection for at least the following reasons.

As noted above, McCormack '179 does not constitute prior art for the instant application under 35 U.S.C. § 103(c). Therefore, citation of the combination of McCormack '179 and Reed '699 against the pending claims is inappropriate. Applicant respectfully submits that the Section 103-based rejection over the combination of McCormack '179 and Reed '699 should be withdrawn.

Having addressed each of the foregoing rejections, Applicant respectfully submits that this application is in condition for allowance. Notification to that effect is earnestly solicited.

Should questions relating to patentability of the claims remain, the Examiner is invited to telephone the undersigned to discuss the same.

Respectfully submitted,

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APPENDIX
MARK UP VERSION SHOWINGS CHANGES MADE

IN THE CLAIMS:

The claims have been amended as indicated below.

26. (Twice Amended) A multilayer breathable film having the combination of properties of:

(i) providing a barrier to microorganisms; and

(ii) providing a barrier to blood and bodily fluids;

said breathable film comprising at least a three-layer film having as a minimum the following structure:

C:D:C;

where C comprises an outer monolithic layer containing a hydrophilic polymeric resin capable of absorbing and desorbing moisture and providing a barrier to water and microorganisms, said C layer being substantially free of particulate filler; and,

D comprises a microporous adhesive core layer for bonding said C layers together,

wherein said C layer substantially prevents the buildup of particulate filler material on a die during formation of said multilayer breathable film, and

wherein said microporous adhesive core layer comprises particulate filler having an average particle size between about .8 microns and about 3

microns, where upon stretching the microporous adhesive the core layer has at least 27.6% microvoids, said [micropores are] microporous adhesive core layer being constructed and arranged to provide the passage of gaseous water but substantially prevent the passage of liquid water.

32. (Amended) A multilayer breathable film having the combination of properties of:

(i) providing a barrier to microorganisms; and

(ii) providing a barrier to blood and bodily fluids;

said breathable film comprising at least a coextruded three-layer film having as a minimum the structure C:D:C; wherein

C comprises an outer monolithic film layer containing a hydrophilic polymeric resin capable of absorbing and desorbing moisture and providing a barrier to water and microorganisms, said C layer being substantially free of particulate filler; and,

D comprises an adhesive core film layer for bonding said C layers together, the adhesive core film layer including micropores, the micropores being constructed and arranged to permit the passage of gaseous water and to provide a barrier to the passage of liquid water;

wherein said adhesive core film layer further comprises particulate filler having an average particle size between about .8 microns and about 3

microns, where upon stretching the adhesive core film layer has at least 27.6% microvoids; and

further wherein the adhesive core film layer is bonded to the outer monolithic film layers along an interface, the bonding at the interface being substantially complete and uniform.